

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/644,387 08/23/00 AGOSTON

G 05213-0541

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HM12/0814

EXAMINER

BAR ID. #	ART UNIT	PAPER NUMBER
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1616  
DATE MAILED:

08/14/01

*WD*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/644,387	AGOSTON ET AL.
	Examiner Barbara P Badio, Ph.D.	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_ .

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-13 and 21-25 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claims \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_ .

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

**First Office Action on the Merits**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-13 and 21-25 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that search and examination of the entire application could be made without serious burden. This is not found persuasive because each of Groups II-VII is drawn to a different method of making 2-methoxyestradiol and, thus, each would require a different search. Therefore, search and examination of the entire application would result in serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Note: Claims 14-20 will be rejoined with the elected Group I upon allowance of said Group in accordance with MPEP § 821.04.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-13 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Amato et al. ('074).

D'Amato et al. teach 2-methoxyestradiol and its effect on cell division (see the entire article, especially Tables 1 and 2, compound #1). The compound and composition taught by the reference are encompassed by the instant claims.

4. Claims 1-13 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. ('168).

Clark et al. teach 2-methoxyestradiol and its effect on intraocular pressure (see the entire article, especially col. 2, compound #2; col. 4, example 2). The compound and composition taught by the reference are encompassed by the instant claims.

5. Claims 1-13 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Fotsis et al. ('900).

Fotsis et al. teach 2-methoxyestradiol and its use for treatment of pathological conditions associated with enhanced angiogenesis (see the entire article, especially col. 2, lines 20-37). The compound and composition taught by the reference are encompassed by the instant claims.

6. Claims 1-13 and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Stewart ('966).

Stewart et al. teach 2-methoxyestradiol and its effect on airway remodeling (see the entire article, especially Abstract; cols. 10-14, examples 1-5). The compound and composition taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-13 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato et al. ('074), Clark et al. ('168), Fotsis et al. ('900) or Stewart('966).

Each of the cited prior art teaches the compound 2-methoxyestradiol and method(s) of using said compound in treatment of a disorder. See each reference as indicated above in #s 3-6.

The instant claims differ from the references by reciting the compound has a purity of greater than 98%. However, purification of a compound to be utilized as a pharmaceutical agent would have been obvious to one having ordinary skill in the art at the present invention. Therefore, the ordinary artisan in the art would have the reasonable expectation that the compound taught by the cited prior art references is in pure form.

***T / phone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

*Barbara Badio*  
Barbara P Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
August 13, 2001